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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,076	12/10/2003	Carlos A. Schuler	0130.00	7962
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NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER PATEL, NIHIR B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,076	Applicant(s) SCHULER ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12.10.2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11.14.06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims **1-21** are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (WO 92/07599).

3. **As to claim 1**, Smith teaches an inhalation device that comprises a housing **2** (see page **18 lines 30-35**); a container **4** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant (see page **18 lines 30-35**); a metering valve **6** in communication with the reservoir, the metering valve **6** being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position (see pages **18 and 19**); and a contact member **18** in the housing, the contact member being moveable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when in the first position and is unable to contact the contact member when in the second position (see pages **18 and 19**).

4. **As to claim 2**, Smith teaches an apparatus wherein the metering valve **6** may be moved to the actuated position only when the contact member is in the first position (see figure **1**; pages **18 and 19**).

5. **As to claim 3**, Smith teaches an apparatus wherein the container **4** and the metering valve **6** are moveable within the housing **2** and wherein when the contact member **18** is in the first position, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is unable to contact the contact member and cannot be moved into the container to the actuated position (see **figure 1; pages 18 and 19**).

6. **As to claim 4**, Smith teaches an apparatus that further comprises a controller **30** adapted to selectively control the movement of the contact member **18** (see **page 19 lines 5-25**).

7. **As to claim 5**, Smith teaches an inhalation device that comprises a housing **2** (see **page 18 lines 30-35**); a container **4** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant (see **page 18 lines 30-35**); a metering valve **6** in communication with the reservoir, the metering valve **6** being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position (see **pages 18 and 19**); and a contact member **18** in the housing **2**, the contact member **18** being moveable between a first position and a second position, wherein a portion of the metering valve **6** is able to contact the contact member **18** when in the first configuration in a manner which allows the metering valve **6** to be moved to the actuated position (see **page 19**).

8. **As to claim 6**, Smith teaches an apparatus wherein the metering valve **6** may be moved to the actuated position only when the contact member **18** is in the first configuration (see **page 19**).

9. **As to claim 7**, Smith teaches an apparatus wherein the container **4** and the metering valve **6** are moveable within the housing **2** and wherein when the contact member **18** is in the first

configuration, the metering valve 6 is able to contact the contact member 18 so that it may be moved into the container 4 to the actuated position and when the contact member 18 is in the second position, the metering valve 6 is able to contact the contact member 18 but cannot be moved into the container 4 to the actuated position (see figure 1 and page 19).

10. As to claim 8, Smith teaches an apparatus wherein the contact member 18 is rigid in the first configuration and is flexible in the second configuration (see page 19).

11. As to claim 9, Smith teaches an apparatus wherein a controller 30 adapted to selectively control the configuration of the contact member 18 (see page 19 lines 5-25).

12. As to claim 10, Smith teaches an inhalation device that comprises a housing 2 (see page 18 lines 30-35); a container 4 comprising a reservoir storing a pharmaceutical formulation which comprises a propellant (see page 18 lines 30-35); a metering valve 6 in communication with the reservoir, the metering valve 6 being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position (see pages 18 and 19); and a contact member 18 in the housing 2, the contact member 18 being moveable between a first position and a second position, wherein when the contact member 18 is in the first condition, the metering valve 6 may contact the contact member 18 so as to allow the metering valve 6 to be moved to the actuated position (see page 19).

13. As to claim 11, Smith teaches an apparatus wherein the first condition is a first position and wherein the second condition is a second position (see page 19).

14. **As to claim 12**, Smith teaches an apparatus wherein first position is a position in the housing **2** where the contact member **18** may contact a portion of the metering valve **6** (see **figure 2 and page 19**).

15. **As to claim 13**, Smith teaches an apparatus wherein the first condition is a first configuration and wherein the second condition is a second configuration (see **page 19**).

16. **As to claim 14**, Smith teaches an apparatus wherein the first configuration is a rigid configuration and the second configuration is a relatively flexible configuration (see **page 19**).

17. **As to claim 15**, Smith teaches an apparatus wherein the metering valve **6** may be moved to the actuated position only when the contact member **18** is in the first condition (see **figure 2 and page 19**).

18. **As to claim 16**, Smith teaches an apparatus wherein the container **4** and the metering valve **6** are moveable within the housing **2** and wherein when the contact member **18** is in the first condition, the metering valve **6** is able to contact the contact member **18** so that it may be moved into the container **4** to the actuated position and when the contact member **18** is in the second condition, the metering valve **6** cannot be moved into the container **4** to the actuated position (see **page 19**).

19. **As to claim 17**, Smith teaches an apparatus that further comprises a controller **30** adapted to selectively control the condition of the contact member **18** (see **page 19**).

20. **As to claim 18**, Smith teaches an inhalation device that comprises a housing **2** (see **page 18 lines 30-35**); a container **4** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant (see **page 18 lines 30-35**); a metering valve **6** in communication with the reservoir, the metering valve **6** being moveable into the container to an actuated position,

wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position (**see pages 18 and 19**); and a contact member 18 in the housing 2, wherein the metering valve 6 may be moved to the actuated position when the metering valve 6 and/or the container 4 is able to contact the contact member 18 and may not be actuated with the metering valve 6 and/or the container 4 is unable to contact the contact member 18 (**see page 19**).

21. As to **claim 19**, Smith teaches an apparatus that further comprises a controller 30 adapted to selectively control when the metering valve 6 may and may not be moved to the actuated position (**see page 19**).

22. As to **claim 20**, Smith teaches an inhalation device that comprises a housing 2 (**see page 18 lines 30-35**); a container 4 comprising a reservoir storing a pharmaceutical formulation which comprises a propellant (**see page 18 lines 30-35**); a metering valve 6 in communication with the reservoir, the metering valve 6 being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position (**see pages 18 and 19**); and a contact member 18 in the housing 2, wherein the metering valve 6 may be moved to the actuated position when the metering valve 6 and/or the container 4 is able to contact the contact member 18 in a rigid configuration and may not be actuated with the metering valve 6 and/or the container 4 is unable to contact the contact member in a rigid configuration (**see page 19**).

23. As to **claim 21**, Smith teaches an apparatus that further comprises a controller 30 adapted to selectively control when the metering valve 6 may and may not be moved to the actuated position (**see page 19 lines 5-25**).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. Claims **22-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (WO 92/07599).

27. **As to claims 22-25**, Smith substantially discloses a method steps of positioning a contact member **18** in a first position where the contact member **18** may contact the metering valve **6** and/or the container **4** to allow the metering valve **6** to be moved to the actuated position; and positioning the contact member **18** in a second position where the metering valve **6** may not be moved to the actuated position.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Smith.

27. **As to claims 26-30**, Smith substantially discloses a method steps of configuring a contact member **18** in a first configuration wherein the contact member **18** may contact the metering

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valve 6 and/or the container 4 to allow the metering valve 5 to be moved to the actuated position; and configuring the contact member 18 in a second configuration wherein the metering valve 6 may not be moved to the actuated position.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Smith.


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nihir Patel


PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
6/23/07